

§ 870.4210

§ 870.4210 Cardiopulmonary bypass vascular catheter, cannula, or tubing.

(a) *Identification.* A cardiopulmonary bypass vascular catheter, cannula, or tubing is a device used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and to interconnect the catheters and cannulas with an oxygenator. The device includes accessory bypass equipment.

(b) *Classification.* Class II (performance standards).

§ 870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) *Identification.* A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

(b) *Classification.* Class II (performance standards).

§ 870.4230 Cardiopulmonary bypass defoamer.

(a) *Identification.* A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiopulmonary bypass surgery to remove gas bubbles from the blood.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) *Identification.* A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system used in extracorporeal circulation to warm or cool the blood or perfusion fluid flowing through the device.

(b) *Classification.* Class II (performance standards).

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§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) *Identification.* A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

(b) *Classification.* Class II (performance standards).

§ 870.4260 Cardiopulmonary bypass arterial line blood filter.

(a) *Identification.* A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions."

[45 FR 7907-7971, Feb. 5, 1980, as amended at 52 FR 17737, May 11, 1987; 66 FR 18542, Apr. 10, 2001]

§ 870.4270 Cardiopulmonary bypass cardiotomy suction line blood filter.

(a) *Identification.* A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

(b) *Classification.* Class II (performance standards).

§ 870.4280 Cardiopulmonary prebypass filter.

(a) *Identification.* A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not used to filter blood.

(b) *Classification.* Class II (performance standards).